REMARKS

Upon entry of this amendment, claims 1-4, 6-9 and 11-14 are pending in the application. Claims 11-14 are newly added. Claims 1-4 and 6-9 are rejected. Reconsideration and allowance of all pending claims are requested in view of the remarks below.

Claim Rejections under 35 U.S.C. 103(a)

Claims 1-4, 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over BANAS et al (5,749,880) in view of KOWLIGI et al (5,466,509). Applicants traverse this rejection. Applicants submit that Banas '880 and Kowligi are not properly combinable, and even if combined are insufficient to support a rejection of claim 1. Furthermore, Applicants submit that Kowligi does not appear to be enabled for the structure as asserted in the Office Action.

Kowligi involves textured, porous, expanded polytetrafluoroethylene (ePTFE), produced in either tubular or sheet form, for use as vascular grafts. See column 1, lines 29-34. Kowligi discloses a method of manufacturing PTFE by knurling, or patterning, prior to expanding and sintering. As described in column 2, lines 51-66, Kowligi discloses forming a PTFE sheet as known in the art, with the additional step of patterning the sheet to make a plurality of sites or defects at which pores will form. At column 4, lines 23-26, Kowligi provides that tubular PTFE is produced in the same fashion, except that the tube is patterned between a mandrel and a roller, impressing the pattern on the outside and inside surfaces of the tube. Importantly, Kowligi at column 1, lines 53-59, references a process in the art for making ePTFE, noting that the sheet is

"expanded and kept expanded during 'sintering'... After sintering, the sheet retains its shape and is ready for use." (emphasis added) Kowligi continues, "[i]t is desired that any technique for increasing the porosity of PTFE be compatible with this process." (emphasis added)

Kowligi does not make any mention of average internodal distance, instead referring to non-uniform distributions. However, the internodal distances non-uniformly distributed across the range of 10-200 microns, relied on by the Office Action, does not appear to be supported by the disclosure. As noted at column 3, line 42 and column 4, line 22, Kowligi discloses internodal distances of 10-50 microns for sheets. Lines 27-29 then mention tubular PTFE exhibits a higher porosity, but no range of porosity is mentioned, only a 200-500% expansion ratio range. The 10-200 range only appears in claim 1. It appears therefore, that Kowligi is unable to sustain a rejection of an average IND of greater than 100 microns. See generally, MPEP § 2121.02.

Even if Kowligi is enabled for INDs greater than 100 microns, Kowligi discloses that PTFE paste is extruded, dried, rolled to the desired thickness, patterned, and then simultaneously expanded and sintered. Kowligi appears to rely on the defects created by the patterning to induce the pores to form and the sintering to stabilize the structure before use.

On the other hand, Banas '880 involves an endoluminal encapsulated stent. As noted at column 21, lines 32-37, Banas discloses that ePTFE grafts preferably comprise initial internodal distances (INDs) within a range of 0.1 to 100 microns. As summarized in the Abstract of Banas, ePTFE coverings are circumferentially applied over the stent member in their unsintered state and sintered during the application of a circumferential pressure to bond the ePTFE around and

through the wall surfaces of the stent. The sintered ePTFE forms a substantially continuous, monolithic and integral encapsulation of the stent. Upon radial expansion of the stent graft, the stent and the ePTFE node-fibril microstructure radially deform. The Abstract also notes that after radial expansion of the stent, a substantial bonded area remains intact and maintains the encapsulation of the stent *in vivo*.

Applicants' claim 1 recites a radially deployable stent wherein biocompatible material of an inner cover and/or biocompatible material of an outer cover has an average internodal distance of greater than 100 microns.

The Office Action asserts that in view of Kowligi it would have been obvious to one of ordinary skill in the art to provide ePTFE of internodal distance greater than 100 microns, by the use of Kowligi, for the inner cover or outer cover of Banas. Applicants assert that the method of Kowligi is not combinable with Banas. Specifically, there is no teaching in the art regarding how the patterning step of Kowligi can be combined with Bana's method of forming the stent or how sintering could simultaneously be done under expansion and compression, as required by the respective references. As an aside, Applicants note that Kowligi makes no mention of stents, ePTFE for stents, or application of ePTFE to stents.

Banas applies coverings over the stent member in their unsintered state and then simultaneously sinters and applies "circumferential pressure to bond the ePTFE around and through the wall surfaces of the stent" such that the "sintered ePTFE forms a substantially continuous, monolithic and integral encapsulation of the stent." See the Abstract of Banas. Therefore, Applicants submit that it would be impossible to conduct sintering under expansion,

as noted in Kowligi. Also, it would not be practical or obvious to apply the patterning as disclosed in Kowligi, as the patterning, expansion and sintering steps of Kowligi must be applied before the item is ready for use and to retain its shape.

Contradictory to the disclosure of Kowligi, the Office Action asserts that it would be obvious to take unsintered, patterned tubes and apply them over a stent and simultaneously sinter and circumferentially compress them to "bond the ePTFE around and through the wall surfaces of the stent" such that the "sintered ePTFE forms a substantially continuous, monolithic and integral encapsulation of the stent." Importantly, Kowligi makes no mention of compressing the ePTFE after patterning and before, or during, sintering. However, Kowligi does note that the ePTFE should be kept expanded during sintering. Column 1, lines 53-59.

According to the Office Action, one would allegedly be motivated to combine the references "as this configuration of the inner and outer covers would form a graft having high porosity to affect an incorporation of tissue to the graft after surgery." However, this assertion ignores the clear teaching of Banas of desiring INDs within a range of 0.1 to 100 microns and that Banas seeks to retain a substantial bonded area maintaining encapsulation of the stent upon expansion of the stent. Applicants note that there is no teaching in the cited references, and none supplied in the Office Action, regarding whether characteristics from Kowligi, such as increased and non-uniform IND distribution over a large range, would be compatible with this and other aspects of Banas. Certainly Banas supports the opposite conclusion by bounding the upper end of the desired IND range at 100.

Also, Banas at column 6, lines 14-24, notes that stents should enable uniform radial expansion without radial constriction or collapse. It then becomes unlikely, and certainly not obvious, that one of skill in the art seeking to modify Banas would want to place an ePTFE tube on the stent of Banas that had a non-uniform distribution over a large range. For example, Kowligi at column 1, line 60 to column 2, line 3, notes that ePTFE with an IND of 8-10 microns feels less pliable and wraps less easily. The ePTFE of Kowligi is asserted to have internodal distances non-uniformly distributed across the range of 10-200 microns, making performance of any part of the ePTFE potentially inconsistent during expansion of a stent.

Applicants submit that regardless of the simultaneous sintering and maintaining of an expanded state during sintering procedure used in Kowligi, Banas' use of the simultaneous sintering and circumferential pressure to bond the ePTFE around and through the wall surfaces of the stent, as taught in Banas, are incompatible with that of Kowligi. It appears that whatever impressions are formed on the PTFE by the patterning of Kowligi would be negated by the sintering and circumferential pressure bonding of the ePTFE around and through the wall surfaces of the stent.

In view of the remarks above, Applicants submit that it would not be obvious for one of skill in the art to have combined Kowligi with Banas.

Even if Kowligi and Banas were combined, Applicants submit that they remain insufficient to support a rejection of claim 1, specifically, Kowligi, in claim 1, recites an ePTFE sheet characterized by having internodal distances non-uniformly distributed across the range of 10-200 microns. Applicants submit that this does not necessarily mean that an average

internodal distance would be greater than 100, as this could result in an average internodal distance of less than 100. Also, the circumferential pressure applied during sintering, sufficient to bond the ePTFE around and through the wall surfaces of the stent such that the sintered ePTFE forms a substantially continuous, monolithic and integral encapsulation of the stent, would appear to be enough pressure to disturb or destroy the small impressions made by the patterning of Kowligi. Therefore, the effect of the impressions would be diminished or destroyed, further diminishing a likelihood of an average IND of greater than 100.

Claims 2 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over BANAS and KOWLIGI as applied to claims 1 and 6 above, and further in view of MYERS et al. (5,735,892). Applicants traverse this objection. In view of the remarks above regarding the insufficiency of Banas and Kowligi, Applicants submit that Myers does not overcome these deficiencies and therefore claims 2 and 7 are patentable over Banas, Kowligi and Myers, at least by way of the dependency from claim 1 or 6.

Applicants also note that claim 2 is patentable over the combination of Banas and Kowligi, as the last paragraph of page 3 admits that Banas and Kowligi do not disclose having an inner cover folded over an outer surface of the stent to form the outer cover.

Claims 3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over BANAS and KOWLIGI as applied to claims 1 and 6 above, and further in view of MYERS et al. (5,735,892). Applicants traverse this objection. In view of the remarks above regarding the insufficiency of Banas and Kowligi, Applicants submit that Myers does not overcome these

deficiencies and therefore claims 3 and 8 are patentable over Banas, Kowligi and Myers, at least by way of the dependency from claim 1 or 6.

Newly-Added Claims

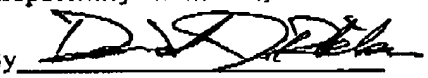
Applicants submit that newly added claims 11-14 are patentable at least by way of their dependency from claim 1 or 6. No new matter is involved, as support for these claims can be found at page 2, lines 8-14, of the specification.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 12-0080, under Order No. ATA-286RCE from which the undersigned is authorized to draw.

Dated: March 23, 2004

Respectfully submitted,

By 

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